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Docket No.: 31894-202098
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Zemel et al.

Art Unit: 1616

Application No: 10/827,296

Examiner: E. J. Webman

Confirmation No: 2568

Filed: April 20, 2004

Atty. Docket No: 31894-202098

For: METHOD OF REDUCING RISK OF A
WEIGHT-RELATED HEALTH DISEASE

Customer No:

26694
PATENT TRADEMARK OFFICE

REQUEST FOR WITHDRAWAL OF THE NOTICE OF WITHDRAWAL FROM ISSUE
UNDER 37 C.F.R. § 1.313(b), AND, IN THE ALTERNATIVE, RESPONSE TO OFFICE
ACTION

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Withdrawal from Issue dated February 7, 2008, Applicants submit the following reply.

Request for Withdrawal begins on page 2 of this paper.

Response to Office Action begins on page 5 of this paper.

**REQUEST FOR WITHDRAWAL OF THE NOTICE OF WITHDRAWAL FROM ISSUE
UNDER 37 C.F.R. § 1.313(b)**

A Notice of Allowance of the pending claims was mailed on September 19, 2007, and the issue fee was paid on October 19, 2007. Then, improperly, before the patent issued, a Notice of Withdrawal from Issue was mailed in this case on February 7, 2008. The Notice states that the application is being withdrawn “in order to apply art under 35 U.S.C. 103.” No other reason was offered for the withdrawal. In fact, no art was applied under 35 U.S.C. § 103. The PTO lacks the statutory authority to issue the Notice of Withdrawal from Issue. Furthermore, the reasons cited for the withdrawal are without merit. Applicants therefore request immediate withdrawal of the Notice of Withdrawal from Issue.

The PTO’s actions in this regard violate the plain text of 35 U.S.C. § 151. The second paragraph of § 151 states that “Upon payment of this sum [i.e., the issue fee], the patent shall issue.” The statute is clear: once the issue fee has been paid, issuance of a patent is required by law, and the PTO no longer has the power to withdraw an application from issue. Here, the issue fee was paid on October 19, 2007. The PTO’s power to prevent issuance of the patent expired that day. Accordingly, the Notice of Withdrawal from Issue is without legal force, and the PTO is compelled by statute to issue the patent in this case.

BlackLight Power Inc. v. Rogan, 295 F.3d 1269, 63 USPQ.2d 1534 (Fed. Cir. 2002) illustrates how rarely a patent may be withdrawn from issue, only in exceptional circumstances. In *Blacklight*, a Group Director took emergency action to withdraw an application from issue where it was apparent that “the applicant was claiming [a physical phenomenon] that [she] knew was contrary to the known laws of physics and chemistry.” *Id.* at 1535. The court deemed it necessary to find the withdrawal to be “within the scope of the Director’s authority . . . when viewed in light of the unusual circumstances of this case.” *Id.*

The emergency circumstances that compelled the result in *BlackLight* do not exist here. The PTO does not claim that the invention violates known physical and chemical laws, nor does it assert any other issue that warrants emergency action in contravention of the clear text of § 151. To the contrary, this application has been competently examined by an experienced Examiner and has been

found to be patentable. The PTO's action in this case is without legal basis. Applicant therefore requests that the Notice of Withdrawal from Issue be withdrawn immediately.

The lack of statutory basis for withdrawing this case from issue becomes even more apparent from review of the Office Action mailed February 7, 2008. The Office Action does not even meet the improper test recited in the Notice of Withdrawal from Issue because it applies no art and it makes no rejections under 35 U.S.C. § 103. Indeed, far from presenting a clear and unmistakable justification for emergency action, the Office Action sets forth meritless rejections and general housekeeping matters that have no bearing on the patentability of the claims, and in any event could have been addressed years ago. This withdrawal needlessly wastes Applicants' time and other resources and does nothing except delay Applicants' receipt of the patent to which it is entitled.

In the Office Action, the PTO purports to reject claims 1-7 and 10-15 under 35 U.S.C. § 102(a) as being unpatentable over Zemel et al. (FASEB J., June 2000, 14(9), 1132-38). This is not a new reference and is not prior art. This reference was submitted to the PTO in an IDS dated April 20, 2004, nearly four years ago. It was individually considered by the PTO in December 2005, more than two years ago. And yet no action was taken on this reference until nearly five months after a Notice of Allowance was issued in this case. This rejection is very easily overcome with a Declaration under 35 C.F.R. § 1.132, submitted herewith and previously submitted for the very same purpose in two other related cases (U.S. Appl. Nos. 10/017,568 (Declaration received by PTO Sep. 13, 2007) and 10/827,307 (received Feb. 14, 2008)). This rejection was needless, it does not affect the patentability of the claims, and in any event it could have been asserted years ago.

The PTO also purports to reject claims 1-6 under 35 U.S.C. § 112, first paragraph, because the term "avoiding health problems" in the preamble to claim 1 allegedly lacks enablement. Applicant disagrees with the rejection, as set forth below. Furthermore, claim 1 has included this term since the claims were submitted to the PTO nearly four years ago. The claims were subjected to scrutiny through four Office Actions, and yet the PTO never expressed any issue with this term until nearly five months after a Notice of Allowance was issued in this case. Thus, this rejection is needless and without merit, and in any event it could have been addressed years ago.

The PTO also purports to reject claims 1-7 and 10-15 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The PTO alleges that the claim term “‘at least about’ with respect to both 773 [mg calcium per day] and 57 [servings of dairy per month] . . . introduce new matter into the claims.” Applicants disagree with this rejection, as set forth below. Furthermore, the claim element “at least about 57 portions of dairy per month” has been included in dependent claims since the original claims were filed almost four years ago. Applicants amended the independent claims to include both claim elements as a result of Examiner’s recommendations, and the amended claims were submitted in a response dated November 21, 2006. The Examiner evaluated these new elements and determined that the claims as amended are patentable. Now, more than a full year later, the very elements that Applicants added, and which the Examiner recommended and subsequently evaluated and approved, are being rejected as introducing new matter. Accordingly, the rejection is erroneous and without merit, and in any event it could have been addressed more than a year ago.

The lack of finality and the unnecessarily dilatory manner in which the PTO has handled this issue has deprived Applicants of its ability to obtain fair prosecution of its application, and has unnecessarily wasted time and money. The only result has been to needlessly delay Applicants’ receipt of a patent for this invention.

Thus, not only does the PTO lack statutory authority to withdraw this case from issue, the reasons cited in the Notice of Withdrawal from Issue are without merit. Accordingly, Applicants request that the Notice of Withdrawal from Issue be withdrawn and that the application again be passed to issue.

However, in the alternative and in the interest of expediency, Applicants address the Examiner’s arguments below.